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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/726,348 | 12/01/2000 | Ying-Fei Wei | PF220P1 | 3638 |

22195 7590 04/09/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

SPECTOR, LORRAINE

| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 3/14/03 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Replacement of Ab-binding limitation with other functional limitation requires further consideration under 112§1.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: 33-39, 60-67, 76-79

Claims objected to:

Claims rejected: 26-32, 40-59, 68-75

However,

☒ Applicant's response would, if entered, overcome the following rejection(s): 112§1-New Matter.

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other Applicants are correct about allowability of claims 33-39.

Lorraine Spector
LORRAINE SPECTOR

Part III: Detailed Office Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/03 has been entered.

Claims 26-79 are under consideration.

The rejection of claims 26-32 and 40-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of applicants' amendments.

Claim Objections:

Applicant is advised that should claims 72-75 be found allowable, claims 76-79 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-59 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein of SEQ ID NO: 2 or as encoded by ATCC 97342 or fragments thereof that have the activity of stimulating the growth of aortic smooth muscle cells, does not reasonably provide enablement for proteins 90% or 95% identical to such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for reasons set forth in paper number 18 at pages 3-4. This rejection is maintained for reasons of record. Applicants traverse in paper number 19, filed 3/14/03 that the narrowing of the claims to recite that the claimed polypeptide "stimulates aortic smooth muscle cell proliferation" overcomes the rejection has been fully considered but is not deemed persuasive. It remains that the specification merely presents an invitation to experiment to find variants, as opposed to specific guidance or working examples of variants. It remains that although proteins that bind and activate EGF receptors were known in the art, and the relative skill in the art of molecular biology is high, the predictability in the art of altering proteins and retaining function is relatively low, especially where, as in this case, the members of the protein family which bind EGF receptors have a low degree of conservation of amino acid sequences. In this case, the similarity to TGF α H3 shown in Figure 2 is very low, and it has not been established that TGF α H3 binds to the common receptor, the EGF receptor. Taken with the lack of working examples, the lack of *specific* direction or guidance as to alterations which could be made, the breadth of the claims, which in their current state read on a very large scope of proteins, the specification fails to provide enablement commensurate in scope with the claims.

The instant specification is not enabling because one cannot, following the guidance presented therein, practice the suggested method without first making a substantial inventive contribution.

Rejections over Prior Art:

Priority Determination: This application is a CIP of 08/778545. As the parent application was found

to lack utility and enablement under 35 U.S.C. § 101 and 112, first paragraph, respectively, priority for this application is set at the current filing date of 12/1/2000.

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 Claims 26-79 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/18203 (Kato et al.), cited by applicants.

20 SEQ ID NO: 7 of Kato et al. is identical to SEQ ID NO: 2 of the instant application. Fragments are disclosed at page 7, and recombinant expression of protein is disclosed, as are fusion
25 proteins and compositions comprising a carrier, see pages 4-7, 9 and 11-14, respectively. The property of stimulating aortic smooth muscle cell proliferation is inherent to the protein of Kato et al.

30 **Advisory Information:**

NO claim is allowable.

35 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

 If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

30 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

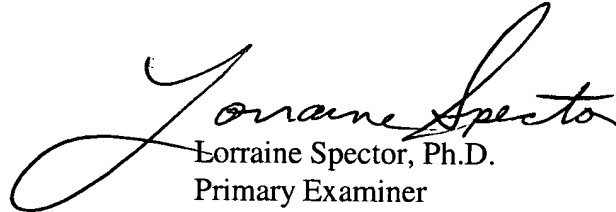
35 Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be

Serial Number 09/726348

Art Unit 1647

retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Lorraine Spector, Ph.D.
Primary Examiner

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6/23/03